Supporting Statement for the Department of Health and Human Services (HHS) Subpart C Research Certification Form

Background

The Office for Human Research Protections (OHRP) is requesting a three-year extension of OMB No. 0990-0473, the HHS Subpart C Research Certification Form, currently approved through July 31, 2023. This information collection request includes three new information elements (*Name(s) of Institutions Relying on the IRB of Record*; *Program Officer's Email Address*; and *the IRB Determination Regarding the Risk Level of the Study*) and clarification in two information elements (Name and address *of the IRB of Record Institution*; and Contact information *for the IRB of record*) on the current Subpart C Research Certification Form.

The purpose of the Subpart C Research Certification Form is to provide a simplified, standardized procedure for institutions to submit subpart C research certifications to OHRP in order to meet the regulatory requirements for including prisoners in non-exempt human subjects research that is conducted or supported by HHS. The form also simplifies the internal process used by OHRP to review and record such certifications, resulting in faster processing while reducing unnecessary and burdensome staff time.

Respondents for this information collection are institutions or organizations which operate the IRB of record that approved the research, or the non-institutional IRBs that serve as the IRB of record.

A. Justification

1. Need and Legal Basis

   Section 491[289](a) of the PHS Act states that the Secretary of HHS shall by regulation require that each entity applying for a grant, contract, or cooperative agreement to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an IRB to review research in order to protect the rights and welfare of the human subjects of such research. The Secretary of HHS has delegated this statutory authority to the Assistant Secretary of Health, and to OHRP. OHRP is responsible for interpreting and enforcing the HHS protection of human subjects regulations at 45 CFR part 46[1].

   Subpart C, 45 CFR part 46, provides "Additional Protections Pertaining to

[1] The pre-2018 HHS Protection of Human Subjects Regulations (or pre-2018 Requirements), codified at subpart A, 45 CFR part 46 (as amended), were originally promulgated in 1991 (56 FR 28012, 28022) and amended on June 23, 2005 (70 FR 36325). The 2018 HHS Protection of Human Subjects Regulations (or 2018 Requirements), codified at subpart A, 45 CFR part 46 (as amended), were originally published on January 19, 2017 (82 FR 7149), and amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497).

Biomedical and Behavioral Research Involving Prisoners as Subjects." Subpart C provides four permissible categories of HHS-conducted or –supported research in which prisoners may be involved (45 CFR 46.306(a)(2)); a waiver was later added in 2003 under 46.101(i) for epidemiological studies which satisfy certain criteria and involve prisoners as subjects (https://www.govinfo.gov/content/pkg/FR-2003-06-20/html/03-15580.htm). This "epidemiological waiver" functions as a narrow fifth category of permissible research. In approving such research, an IRB reviewing research involving prisoners to which Subpart C applies must make seven findings, including the finding that the proposed research represents one of the permissible categories of research under section 46.306(a)(2) (45 CFR 46.305(a)). Pursuant to 45 CFR 46.305(c), an institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has approved the research in accordance with section 46.305(a). Section 46.305(c) states that "The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the [IRB] under this section have been fulfilled."

Under OHRP's current implementation of this certification requirement, the institution must complete and submit the Subpart C Certification form, https://oash.force.com/ohrpwebforms/s/prisoner-web-form in conjunction with a copy of the research proposal. For purposes of certification, the term "research proposal" includes:

- the IRB-approved protocol and consent forms, if any;
- any IRB application forms required by the IRB; and
- any other information requested or required by the IRB to be considered during IRB review

2. Information Users

To standardize and facilitate the processing and recordation of such certifications, the Subpart C Research Certification Form requests the following information, for the following purposes:

(a) The name and address of the institution that operates the IRB of record which approved the research (or the name and address of the non-institutional IRB that serves as the IRB of record), name(s) of institutions relying on the IRB of record, and the name, title, or position, mailing address, phone number, and electronic mail address of the contact person for the institution or organization providing the certification information.

(Note: submitting the following information for the contact person is optional: title or position)

Purpose: OHRP will use this information to communicate with the institution or the IRB of record directly to ask questions, forward information, and send

electronic mail to that contact person.

(b) Relevant grant number, granting institution, and name and email address of granting institution's program officer.

Purpose: This information serves to specifically identify the study at issue, and provide granting institution contact information for future correspondence for questions or notification of final disposition.

(c) IRB Registration number

Purpose: OHRP uses this information to identify the specific IRB which conducted the subpart C review. OHRP posts a list of registered IRBs on its website, including the name and location of each IRB and the name and location of the organization operating the IRB.

(d) OHRP Assurance number

Purpose: OHRP collects this information to be able to contact the institutional official at the site engaged in human subjects research, if necessary.

(e) Study title, name and degree of Principal Investigator, and brief summary of the protocol

Purpose: OHRP uses this information to identify the research study, responsible investigator, and the research context.

(f) Dates of IRB approval under Subpart C

Purpose: The dates of initial and/or Subpart C review verify IRB review and approval, as required by 45 CFR 46.111 and 46.305(a).

(g) IRB risk determination of minimal risk or greater than minimal risk

Purpose: The IRB risk determination of minimal risk or greater than minimal risk is necessary for OHRP to, if appropriate, revise the permissible 45 CFR 46.306(a)(2) category of research from the one designated by the reviewing IRB. Section 46.306(a)(2) allows four permissible categories of subpart C research. Sections 46.306(a)(2)(i) and (ii) apply only to minimal risk research, while (iii) and (iv) do not have a risk limit. In circumstances in which the IRB erroneously placed the research study in categories 46.306(a)(2)(iii) or (iv) and OHRP determines that the elements of those categories are not satisfied and that the study may be more appropriately categorized as 46.306(a)(2)(i) and (ii), OHRP may change the study's category determination. To do so, OHRP must know the IRB's determination of risk level to ensure the study does not exceed the limitations for the revised category.

(h) The applicable permissible category or categories of research, and a rationale as to why the research represents the specified category.

Purpose: In compliance with 45 CFR 46.305(a), the IRB must determine that the proposed research represents a permissible category of research under 45 CFR 46.306(a)(2) or satisfies criteria for the epidemiological waiver.

(i) Certification that the research has been approved by an IRB that has adhered to all responsibilities prescribed for IRBs under subpart C, that the research under review represents one of the categories of permissible research under 45 CFR 46.306(a)(2) or falls within the epidemiological waiver, and that the IRB has made the determinations required by 45 CFR 46.305(a)(2)-(7).

Purpose: This certification is required by 45 CFR 46.305(c), and by the terms of the epidemiological waiver.

(j) Names of institutions relying on the reviewing IRB as the IRB of record for the subpart C review and certification of this study.

Purpose: In cases in which the reviewing IRB is acting as the IRB of record on behalf of multiple institutions, this provides clarity regarding to which institutions the certification applies.

3. Improved Information Technology

OHRP uses information technology to allow for electronic completion and submission of the collected information on the Subpart C Certification form which is automatically transferred to a database. If an institution or organization is unable to submit the information electronically, it can contact OHRP by phone, 240-453-8141 or email, subpartc@hhs.gov, to discuss an alternative submission process.

4. Duplication of Similar Information

There is no duplication of similar information relevant to this information collection. OHRP is the only entity exercising regulatory oversight of the Subpart C certification requirement for HHS-conducted or -supported non-exempt research involving prisoners.

5. Small Businesses

The information collection through the Subpart C Certification Form is simple and straightforward and represents the minimum amount of information necessary to satisfy the Subpart C certification requirements. The information collection will not have a significant economic impact on a substantial number of small entities.

6. Less Frequent Collection

   The Subpart C Certification Form must be submitted prior to any HHS-conducted or -supported non-exempt human subjects research interaction or intervention with prisoners. The certification must be resubmitted only if there is a change in the IRB-approved category of permissible research (45 CFR 46.305(a)).

7. Special Circumstances

   None.

8. Federal Register Notice/Outside Consultation

   Public comments were solicited for a 60-day period in the *Federal Register* published on March 16, 2023 (88 FR 16275). No comments were submitted.

9. Payment/Gift to Respondent

   No payments or gifts are provided to the respondents.

10. Confidentiality

    The public is required to submit a Freedom of Information Act (FOIA) request to request non-public Subpart C Certification Form information.

    The information in this database is not public and will only be made available to the public through a FOIA request.

11. Sensitive Questions

    No sensitive information is being collected by the Subpart C Certification form.

12. Burden Estimate (Total Hours & Wages)

    The estimate of the number of respondents is based upon the current number of institutions certifying HHS-conducted or -supported subpart C non-exempt human subjects research to OHRP. In 2021, OHRP received fifty certifications from twenty-nine institutions or organizations and one hundred percent of the respondents submitted their certification information electronically. We project that annually; thirty institutions will submit certifications: twenty-five of the institutions will submit two certifications and five of the thirty institutions will submit three certifications.

    The burden is estimated to average one hour per Subpart C Certification Form and the total annual burden hours are projected to be sixty-five.

12a. Estimated Annualized Burden Hours

Form name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden hours
Subpart C Certification Form	25	2	1.0	50
Subpart C Certification Form	5	3	1.0	15
Total				**65**

We expect that respondents will be research staff persons (to include IRB administrators and Human Protection Administrators), at organizations and institutions. The hourly wage is estimated to be an average $41.35 and the total estimated annualized burden cost is estimated to be $2,681.25.

12b. Estimated Annualized Burden Costs

Form Name	Number of Respondents	Burden Hours	Hourly Wage	Total Respondent Costs
Subpart C Certification Form	25	50	$41.25	$2,062.50
Subpart C Certification Form	5	15	$41.25	$618.75
Total				**$2,681.25**

13. Capital Costs (Maintenance of Capital Costs)

There are no direct capital costs to respondents other than the time to review the instructions and to complete the Subpart C Certification Form.

14. Cost to Federal Government

The estimated annual Federal Government cost is $137,701: $54,701 for reviewing and accepting Subpart C certifications and $87,000 for operating the database.

15. Program or Burden Changes

The annual burden estimates changed compared to the current burden estimates. The changes

are due to agency adjustments. The total annual burden in the current OMB-approved information collection (eighty hours and $1,392.80, respectively) is projected to be sixty-five hours and $2,681.25, respectively, in this information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

    There are no plans to publish or tabulate the information.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    No exception is requested.

B. Justification of Information Employing Statistical Methods

Not Applicable

LIST OF ATTACHMENTS

Attachment 1 – Legal Authorities

a. 42 U.S.C Section 289
b. 45 CFR 46 (pre-2018 Requirements
c. 45 CFR 46 (2018 Requirements)

Attachment 2 – Subpart C Certification Form